

## R E M A R K S

Claims 1 and 3-11 are now in this application, and are presented for the Examiner's consideration.

### Information Disclosure Statement

An Information Disclosure Statement is being filed concurrently with this Amendment, along with payment of the required fee of \$180.00.

Also enclosed therewith is a copy of French Patent No. 2,801,179, which issued from French Patent Application No. 99/14729, the relevance of which is discussed at page 1 of the present application. This also corresponds to U.S. Patent No. 6,823,649 which is also cited in the Information Disclosure Statement. The above satisfies the requirement for a concise explanation of the French Patent.

In addition to citation of the French patent, citation is also made of references cited in co-pending Application No. 10/539,266, cited by the Examiner in the obviousness-type double patenting rejection, discussed below, and in this regard, also enclosed is a copy of EP 1040824.

Further, U.S. Patent No. 6,000,403, which was cited in the counterpart European application is being cited therein, as well as U.S. Patent No. 4,808,172 cited in the corresponding Chinese application.

It is requested that the Examiner acknowledge entry and consideration of these references.

#### Prior Art Rejections

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,826,259 to Bailey.

However, the limitations of claim 2 have been incorporated into claim 1, thereby effectively rewriting claim 2 in independent form. Since Bailey was not applied against claim 2, it is submitted that this rejection is no longer applicable.

Bailey fails to disclose or even remotely suggest the limitations of a pouch fixed to the inside face of one of the two separable parts, with the pouch comprising an applicator, and the blister being housed in the pouch, such that the applicator is impregnated with the substance when the blister is broken. Rather, at most, Bailey discloses two separable parts with a blister therein, without any further structure of the claimed pouch.

Accordingly, it is respectfully submitted that the rejection of claim 1 under 35 U.S.C. §102(e) has been overcome.

Claims 1 and 9 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,695,515 to Fleury.

Again, the limitations of claim 2 have been incorporated into claim 1, thereby effectively rewriting claim 2 in

independent form. Since Fleury was not applied against claim 2, it is submitted that this rejection is no longer applicable.

As with Bailey, Fleury fails to disclose or even remotely suggest the limitations of a pouch fixed to the inside face of one of two separable parts, with the pouch comprising an applicator, and the blister being housed in the pouch, such that the applicator is impregnated with the substance when the blister is broken. Rather, at most, Fleury discloses two separable parts with a blister therein, without any further structure of the claimed pouch.

Accordingly, it is respectfully submitted that the rejection of claims 1 and 9 under 35 U.S.C. §102(e) has been overcome.

Claims 1-3 and 5-8 were rejected under 35 U.S.C. §103(a) as being obvious from U.S. Patent No. 5,562,642 to Smith et al in view of U.S. Patent No. 6,547,468 to Gruenbacher et al.

Smith et al is directed to an arrangement in which there is a single pad 20, 22 attached to the inside faces of the two separable parts 12, 13 of the protective cover. However, there is no disclosure or suggestion anywhere in Smith of providing a rupturable blister as in Gruenbacher et al.

It was stated that it would have been obvious to replace the applicator pads of Smith et al with the applicator (containing the blister 12) of Gruenbacher et al in order to provide controlled release of the substance.

However, it is pointed out that it is not the mere possibility of combining the references that must be taken into consideration, but rather there must exist some logical reason or some suggestion in the art for combining the references. W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983); ACS Hospital Systems, Inc. v. Montefiore Hospital et al.; 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984); In re Imperato, 179 U.S.P.Q. 730, 732 (C.C.P.A. 1973).

It is submitted that there is no suggestion or logical reason to modify Smith et al in view of Gruenbacher et al, absent the teachings of the present claimed invention. Smith et al is directed to a flat sheet-like structure, and would not accommodate a blister therein. Further, there is no pouch in Smith that encompasses sheets 20, 22 and which pouch is secured to an inside face of one of the separable parts 12, 13.

Gruenbacher et al, on the other hand, does not provide any protective cover, but rather, the sheet surrounding the blister in Gruenbacher et al is the applicator itself. Thus, the outer sheet 15 is a permeable membrane (column 3, line 38). The same holds true as to outer sheet 64 in the embodiment of Fig. 6 (column 8, lines 1-20). There is no disclosure or even a remote suggestion of a protective cover in Gruenbacher et al, let alone one having an inner surface to which a pouch having a blister therein is secured, as claimed herein.

In fact, not only is there no logical reason or suggestion in the art for combining the references, but Smith et al actually teaches away from such a combination.

Smith states that a package equipped with a breakable reservoir therein having a weak point is improper to use due to unexpected rupture or leakage in transportation. Specifically, Smith et al states at column 3, lines 11-22: "... problems may occur because of premature leakage or evaporation of the liquid contents from the inner chamber of the dispensing package into the external applicator due to a premature break in the fracture line. If the overwrap becomes torn or punctured, the applicator may become uncovered and contaminated, and the liquid substance prematurely dispensed."

Further, Smith et al states at column 3, lines 45-50: "A disadvantage of packaging devices that release their contents by rupturing a score line in the container wall is that flexing of the package prior to use may cause the fracture line to split apart prematurely, thus causing unwanted leakage or premature dispersal of the contents. Conversely, the score line may be constructed such that it is difficult to break."

Therefore, Smith et al designed the system thereof to avoid these problems in a system of the type disclosed by Gruenbacher et al. See column 3, lines 51-63 of Smith et al.

There is thus evidence in Smith et al against combining Smith et al with the rupturable blister of Gruenbacher et al.

Thus, one skilled in the art, upon reading Smith et al, would seek to avoid the structure of Gruenbacher et al.

Upon this background, Smith et al has adopted use of an immersed pad 20, 22, instead of such a reservoir, capsule, ampule or blister, in order to avoid this risk.

Further, as discussed above, Gruenbacher et al discloses an applicator equipped with a dosing reservoir. This reservoir comprises two chambers to control liquid flow inside an applicator. As stated above, there is not even a remote suggestion regarding use of a protective cover, as claimed in the present application, in Gruenbacher et al.

It is further noted that, with the structure of Gruenbacher, it is difficult to pour the liquid uniformly to the surface of applicator. The liquid inside the reservoir will flow out only within a localized area, which provides a disadvantage that is overcome with the structure of the present claimed invention.

It is therefore submitted that, not only is there no suggestion or logical reason to combine the references, and not only does Smith et al teach away from such a combination, but also, it would be difficult for a person skilled in the art to combine these inventions.

A new claim 11 has been added, which is effectively a combination of pending claims 1, 3, 5 and 6, and the same arguments made above, apply to this claim as well.

Therefore, on the basis of the present claimed invention, the user can break the blister easily inside the applicator and immerse the applicator with liquid by only applying sufficient finger pressure without opening the protective cover. See page 2, lines 8-15 of the present application. Until the protective cover is opened, however, the substance inside the package does not leak.

During use, a person can easily open (peel-off) the protective cover, so that application to the skin is very convenient. Handling is very easy because the applicator is attached to the protective cover.

The operation is therefore a one-touch operation that is very easy to use, and the user has no risk of contamination by the substance. The structure shown in Fig. 4 has the further advantage that the user will not feel any irritation during the applying operation since the applicator is separated from the peeled-off junction line 35. This also provides a distinct advantage of the present invention.

Accordingly, it is respectfully submitted that the rejection of claims 1-3 and 5-8 under 35 U.S.C. §102(b) has been overcome.

Claim 4 was rejected under 35 U.S.C. §103(a) as being obvious from U.S. Patent No. 5,562,642 to Smith et al in view of U.S. Patent No. 6,547,468 to Gruenbacher et al, and further in view of U.S. Patent No. 4,762,124 to Kerch et al.

The remarks made above in regard to Smith et al and Gruenbacher et al are incorporated herein.

Kerch et al was merely cited for teaching the use of cotton wool 20 inside an applicator 10 with a permeable membrane 22. However, Kerch et al fails to cure any of the aforementioned deficiencies of Smith et al and Gruenbacher et al.

Accordingly, for the same reasons given above, it is respectfully submitted that the rejection of claim 4 under 35 U.S.C. §102(b) has been overcome.

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being obvious from U.S. Patent No. 5,562,642 to Smith et al in view of U.S. Patent No. 6,547,468 to Gruenbacher et al, and further in view of U.S. Patent No. 6,695,515 to Fleury and U.S. Patent No. 5,511,689 to Frank.

The remarks made above in regard to Smith et al, Gruenbacher et al and Fleury are incorporated herein.

Frank was merely cited for teaching an adhesive dressing 1 and cover 4 applicable to the external surface of a film 6 with the outside surface of dressing 1 weakly secured to an inside face cover 4. However, Frank al fails to cure any of the aforementioned deficiencies of Smith et al, Gruenbacher et al and Fleury.

Accordingly, it is respectfully submitted that the rejection of claims 9 and 10 under 35 U.S.C. §102(b) has been overcome.



### Double Patenting

Claims 1-10 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending Application No. 10/539,266 in view of U.S. Patent No. 6,547,468 to Gruenbacher et al.

Specifically, it was stated that claims 1-12 of co-pending Application No. 10/539,266 merely lack the breakable blister, and that U.S. Patent No. 6,547,468 to Gruenbacher et al teaches an applicator comprising a pouch 10 with blister 12 housed within the pouch for the controlled release of the substance (see for example column 2, lines 56-65 of U.S. Patent No. 6,547,468 to Gruenbacher et al). It was therefore concluded that it would have been obvious to one skilled in the art to provide the applicator of claims 1-12 of co-pending Application No. 10/539,266 with a blister as taught by U.S. Patent No. 6,547,468 to Gruenbacher et al in order to provide controlled release of the substance.

First, it is submitted that the addition of Gruenbacher et al far exceeds the limits of an obviousness-type double patenting rejection. Gruenbacher et al provides another element which is not disclosed or even remotely suggested by co-pending Application No. 10/539,266, and is therefore improper.

Co-pending Application No. 10/539,266 merely discloses the use of an impregnated applicator inside a package. There is no

disclosure or even a remote suggestion of using a rupturable blister inside of an applicator (pouch), which in turn, is secured inside of a protective package.

In any event, it is submitted that the amendment of claim 1 herein to include the limitations of claim 2 patentably distinguishes from claims 1-12 of co-pending Application No. 10/539,266. It is noted that it is the claims of the two patent applications which must be compared in an obviousness-type double patenting rejection, and not the disclosures. Therefore, even if the disclosure of Gruenbacher et al is combined with co-pending Application No. 10/539,266, which applicant argues is inappropriate, this still does not change the claims of the two co-pending patent applications, and therefore, has no relevance on the question of obviousness-type double patenting.

Specifically, as discussed above, claim 1 of the present application now requires three distinct elements, namely:

a protective cover made of two separable parts of leakproof material,

a breakable leakproof blister containing one dose of the substance, and

a pouch comprising an applicator.

Claim 1 further requires an association between the parts as follows:

the blister is housed in the pouch,

the pouch is fixed to an inside face of one of the two separable parts, and

the applicator is impregnated with the substance when the blister is broken.

Therefore, it is submitted that the amendment to claim 1 which adds all three elements in a single package, namely, the protective cover, the pouch and the blister, and the arrangement between these elements, patentably distinguishes from co-pending Application No. 10/539,266, taken alone or even with the combination of Gruenbacher et al.

This is because co-pending Application No. 10/539,266 does not disclose a blister, and therefore, cannot claim the blister as part of the claimed combination.

Further, MPEP 804 states that "The 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining in at least one of the applications."

Section 804 of the MPEP further states: "If a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that

rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

The present application is earlier filed than cited Application No. 10/539,266, and the rejection of Application No. 10/539,266, is on different grounds. Therefore, if the Examiner finds that the 'provisional' nonstatutory obviousness-type double patenting rejection is the only rejection remaining after the filing of this Amendment, the Examiner should withdraw this rejection in the present application.

Accordingly, it is respectfully submitted that the provisional rejection on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending Application No. 10/539,266 in view of U.S. Patent No. 6,547,468 to Gruenbacher et al, has been overcome.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

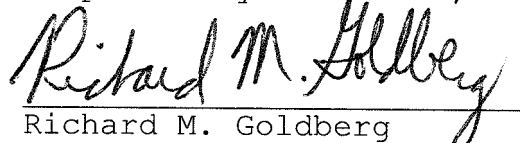
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which may be required, or credit any overpayment to Deposit  
Account No. 07-1524.

In view of the foregoing amendments and remarks, it is  
respectfully submitted that Claims 1 and 3-11 are allowable, and  
early and favorable consideration thereof is solicited.

Respectfully submitted,

A handwritten signature in cursive script that reads "Richard M. Goldberg". The signature is written in dark ink and is positioned above a horizontal line.

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